Effects of 5 or 10 gram of a protein hydrolysate on serum insulin and glucose levels in patients with type 2 diabetes mellitus

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5 and 10 grams of a protein hydrolysate effectively increase insulin secretion and lowers plasma glucose levels after a carbohydrate load in type 2 diabetes mellitus (DM-2)

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20972

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: DSM Food Specialties
Overige ondersteuning: DSM Food Specialties

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum concentrations and AUC of glucose and insulin

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

There is accumulating evidence that amino acids such as leucine play a role as insulin secretagogues. One possible clinical application that is currently explored is a protein hydrolysate. Research with this product has shown that co-ingestion of this product with carbohydrate augments the insulin response and enhances glucose disposal.

Previous experiments were carried out with a relatively high dose of protein. Hence, information on interventions with a lower protein load is necessary. Part I of the current study will address the efficacy of 5 and 10 g of the hydrolysate in lowering blood levels of insulin and glucose in patients with type 2 diabetes mellitus (T2DM).

Objectives:

The objective of this study is to demonstrate the efficacy of a single 5-g and 10-g dose of the hydrolysate on blood levels of insulin and glucose in patients with T2DM.

Study Design:

Randomized, placebo-controlled, double-blind, cross-over study with 3 study-days, separated by 7-day intervals.

Patients:

The study will be carried out in 12 patients, 18 - 70 years of age, with an established diagnosis of T2DM treated by oral anti-diabetic therapy for at least 3 years.

Treatments:

The treatments will consist of a drink that will be freshly prepared prior to use. The drink will

be administered as a single oral bolus (300 mL) containing 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 0, 5, or 10 g of the hydrolysate.

Drinks will be flavored by adding 0.2 g sodium saccharinate, 1.8 g citric acid, and 5 g cream vanilla flavor (Quest International) per liter of beverage.

Study parameters:

Serum concentrations and AUC of glucose and insulin.

Doel van het onderzoek

5 and 10 grams of a protein hydrolysate effectively increase insulin secretion and lowers plasma glucose levels after a carbohydrate load in type 2 diabetes mellitus (DM-2)

Onderzoeksopzet

Baseline, 15, 30, 45, 60. 90 and 120 minutes

Onderzoeksproduct en/of interventie

The treatments will consist of a drink that will be freshly prepared prior to use. The drink will be administered as a single oral bolus (300 mL) containing 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 0, 5, or 10 g protein hydrolysate

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Males or females, 18-70 years old.

2. Fasting glucose level > 7 mmol/L after 2 days refraining from medication.

3. Are on stable medication with biguanides for at least 3 months.

4. Prepared and able to give written informed consent;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of insulin, sulfonylurea derivatives, meglitinides or other antidiabetic drugs except biguanides.

2. BMI > 35 kg/m2.

3. Females who are pregnant, have the intention to become pregnant within the study period, or who are lactating.

4. A present and clinically significant history of ischemic heart disease (such as angina pectoris with an incidence of more than one attack/month), acute myocardial infarction within one year prior to the study or congestive heart failure (defined as NYHA class III or IV).

5. Uncontrolled hypertension.

6. Active, proliferative retinopathy.

7. Active or history of liver disease or impaired renal function (defined as a creatinin clearance calculated with the Cockcroft-Gault formula below 60 ml/min).

8. Participation in a trial within 3 months prior to the start of the study or more then 4 times a year.

9. Loss of 250 ml or more of blood within 3 months prior to screening.

10. Any clinical condition, including use of co-medication or laboratory test results that in the opinion of the investigators may jeopardize the health status of the participants.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2008
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-02-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1192
NTR-old	NTR1237
Ander register	MEC LUMC : P07200-1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A